13.35% of the acute reference dose. The actual exposures are likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD (acute or chronic), because the RfD represents the level at or below which exposure will not pose appreciable risk to human health. DWLOC for adults both acute (9,860 ppb) and chronic (5,936 ppb) are several orders of magnitude above the conservative DWEC for acute (122 ppb) and chronic (37 ppb) worst case scenarios. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to residues of pyrimethanil.

2. *Infants and children*. The relevant toxicity studies as discussed in the toxicology section above show no extra sensitivity of infants and children to pyrimethanil, therefore, the FQPA safety factor can be removed. Using the assumptions and data described in the exposure section above, it is concluded that dietary risk from the proposed uses of pyrimethanil are acceptable for all infant and children sub-populations examined. The most highly exposed sub-population was non-nursing infants for both the chronic and acute analyses. The sub-population non-nursing infants utilizes 0.9% (0.001563 mg/kg bw/day) of the chronic reference dose and 13.35% (0.040040 mg/kg bw/day) of the acute reference dose. All other infant and children populations have less exposure. The chronic and acute drinking water levels of concern for children (1,684 ppb and 2,600 ppb respectively) are well above the conservative drinking water estimated concentrations for chronic and acute scenarios. The chronic DWEC is 37 ppb and the acute DWEC is 122 ppb. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of pyrimethanil.

F. International Tolerances

Maximum Residue Limits for pyrimethanil have not been established by the Codex Alimentarius Commission.

[FR Doc. 03–3695 Filed 2–13–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0020; FRL–7289–9]

Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide microbial agent in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0020, must be received on or before March 17, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; e-mail address: bacchus.shanaz@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0020. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly

available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0020. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2003–0020. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0020.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0020. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7.To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and record keeping requirements.

Dated: February 6, 2003.

Phil Hutton,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 and The Arizona Cotton Research and Protection Council

PP 8E5001

EPA has received a pesticide petition (PP 8E5001) from Interregional Research Project Number 4 (IR–4), New Jersey Agricultural Experiment Station, Technology Center, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue Phoenix, Arizona 85040–2933 proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.1206 by establishing an amendment/expansion of an existing tolerance exemption for the microbial pesticide *Aspergillus flavus* AF36 in or on the food and feed commodity cotton and its by products.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, the aforesaid Interregional Research Project Number 4 (IR–4), has submitted the following summary of information, data, and arguments in support of the pesticide petition on behalf of the Arizona Cotton Research and Protection Council, however EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product name and Proposed Use Practices

Aspergillus flavus AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, is proposed for application to cotton to reduce the incidence of aflatoxin producing strains of*Aspergillus flavus* and thereby reduce aflatoxin contamination of cottonseed. When applied just prior to flowering, *Aspergillus flavus* AF36 which does not produce aflatoxin, competitively excludes aflatoxin producing *Aspergillus flavus* strains without increasing *Aspergillus flavus* in the environment in the long term. Sterile wheat seed colonized with *Aspergillus flavus* AF36 is applied at 10 lb of end-use product (total amount of active ingredient less than 0.01 lb/acre) per acre. The pesticide is currently being used in certain counties in the States of Arizona and Texas under an Experimental Use Permit (EPA Reg. No. 69224–EUP–1). The current submission proposes to establish a permanent exemption from tolerance for residues of *Aspergillus flavus* AF36 on cotton and its byproducts.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The pesticide and corresponding residues are identified as *Aspergillus flavus* AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*.

2. *Magnitude of residue at the time of harvest and method used to determine the residue. Aspergillus flavus* AF36 is a naturally occurring fungus isolated from cottonseed produced in the Yuma Valley of Arizona. *Aspergillus flavus* AF36 has been shown to be naturally and consistently associated with commercial cotton grown in Arizona. Other than immediately after application, the overall quantity of *Aspergillus flavus* at time of harvest on cottonseed grown in fields where *Aspergillus flavus* AF36 has been applied and has been shown to be similar to levels on cottonseed grown in fields where no application was made. *Aspergillus flavus* is a widespread fungus. It is particularly well adapted to the hot desert regions of Arizona where it is widespread in the environment. The communities of *Aspergillus flavus* in the desert and in agricultural fields are naturally composed of both aflatoxin producing (toxigenic) and aflatoxin non-producing (atoxigenic) strains. Both atoxigenic and toxigenic strains have been found on essentially all plant material and soils in the desert valleys of Arizona. The goal of applications is to increase the percent of the *Aspergillus flavus* community composed of the atoxigenic strain AF36 and to decrease the percent of *Aspergillus flavus* that produces aflatoxins on the crop and in the fields.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An exemption from the requirement of a tolerance for residues of the microbial pesticide *Aspergillus flavus* AF36 in/on cotton is being proposed for cotton treated in Arizona and Texas. *Aspergillus flavus* isolate AF36, when applied to the soil just prior to bloom has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Aflatoxin levels in cottonseed products are regulated by the Food and Drug Administration (FDA). FDA does not allow cottonseed products containing aflatoxin at 20 parts per billion (ppb), or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin above 300 ppb, to be used for feeding beef cattle. All lots of the active ingredient (*Aspergillus flavus* isolate AF36) and the formulated products are monitored for aflatoxin production as part of a rigorous quality control program. Starter cultures of *Aspergillus flavus* isolate AF36 used in the production of the end-use product are always screened for strain identity by vegetative

compatibility, and for aflatoxin production using thin layer chromatography and appropriate standards. Quality control standards are zero tolerance in the starter cultures and in the formulated product for aflatoxin production, and for *Aspergillus flavus* not identified as *Aspergillus flavus* isolate AF36. *Aspergillus flavus* AF36 has never been found to produce aflatoxin.

C. Mammalian Toxicological Profile

An acute oral toxicity test was performed whereby a single oral dose of 5,000 milligrams/kilogram body weight (mg/kg/bwt) per animal of *Aspergillus flavus* AF36 colonized wheat seed was administered by gavage to five male and five female Sprague Dawley rats. The oral LD_{50} of *Aspergillus flavus* AF36 was determined to be greater than 5,000 mg/kg rat body weight. No clinical signs were observed during the 14–day study and no abnormalities or adverse effects were observed in any of the rats upon necropsy.

An initial pulmonary rat study resulted in lethality in a significant number of animals treated with either the live *Aspergillus flavus* AF36 in Tween 80 or heat killed *Aspergillus flavus* AF36 in Tween 80. Onset of symptoms was rapid after dosing with all deaths occurring by day 4 of the study. All rats surviving to day 4 of the study recovered and all rats sacrificed (as scheduled) on day 8 or day 15 of the study had totally eliminated viable *Aspergillus flavus* AF36 from the lungs, caecal contents, and feces. There was no evidence of infectivity. The aetiology of deaths was unclear. It appeared that *Aspergillus flavus* AF36 prepared as a test substance with Tween 80 caused a severe acute inflammatory response. Retrospective literature review and consultation with a toxicologist supported the theory that the responses were a result of a synergism with Tween 80 and/or of Tween 80 breakdown products formed during preparation of the spore suspension test substance.

A second rat pulmonary study was therefore undertaken. In the second study the conidia were both washed from the wheat and suspended in sterile physiological saline instead of Tween 80. Animals (2 male and 2 female for each treatment level) were dosed at 0, 10^5, 10^6, 10^7, and 10^8 colony forming units per rat. There were no clinical signs in any of the treatment groups considered to be associated with the test substance. Rats were sacrificed at day 8 without treatment associated mortality. No abnormalities were observed in any of the animals at the macroscopic examination at termination.

Based on these two mammalian studies, the petitioner concludes that *Aspergillus flavus* AF36 does not present either a toxicological or an infectious risk to mammals. Data waivers were requested for the following toxicology studies: Acute dermal toxicology/pathology, primary dermal irritation, primary eye irritation, and acute intraperitoneal toxicology/pathology effects of the microbial pesticide. The following rationales were used as a basis for the data waiver requests:

- Researchers and other workers have worked with *Aspergillus flavus* AF36 at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to 1998) and in hand-picked field plots (1989 to 1994) without report of any adverse health effects.
- *Aspergillus flavus* AF36 is widely distributed in the environment and its occurrence is natural.
- The label will require applicators and other handlers to wear Personal Protective Equipment (PPE) such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N–95, P–95, or R–95, coveralls, long sleeved shirt and long pants, and shoes plus socks, and goggles, to mitigate against dermal and primary eye irritation exposure.

The pesticide is to be applied aerially by mixers/handlers and applicators who are licensed and trained to handle restricted materials. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre. Applications of AF36 do not significantly impact the total amount of *Aspergillus flavus* in the soil or crop, but only change the proportion of the AF36 strain in relation to the overall soil population. Since the product is applied to cotton fields as a granular formulation on colonized wheat seeds, exposure from drift is minimal.

In addition, the following rationales were advanced in support of the data waiver requests for acute dermal toxicity and primary dermal irritation. These studies were waived during the experimental use program, based upon the lack of toxicity in animals dosed orally. While other *Aspergillus flavus* strains have been reported to be dermal sensitizers, this testing is not warranted, since the aerial method of application and the PPE required on the label will mitigate dermal exposure to workers and pesticide handlers. The acute intraperitoneal study was waived based upon the lack of toxicity in animals dosed orally and by pulmonary/intratracheal instillation.

Genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity testing were not performed, since no adverse effects were observed in the acute toxicology study Tier 1 studies. Tier II (885.3550), subchronic toxicology study (EPA OPPTS 885.3600) and chronic feeding studies (guideline 152–50) are only required if triggered by adverse effects observed in Tier I studies.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food. Aspergillus flavus* AF36 is a naturally occurring organism, which does not produce aflatoxin and is thus safer than the aflatoxin-producing *Aspergillus flavus* isolates. Proposed uses and application rates will not result in increases in the total population of *Aspergillus flavus* on the mature crop beyond naturally occurring background levels. FDA does not allow cottonseed products containing aflatoxin at 20 ppb or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin levels above 300 ppb, to be used for feeding beef cattle.

Aspergillus flavus AF36, when applied to the soil just prior to bloom, has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Furthermore, the proposed use and application rate will not increase exposure of humans to *Aspergillus flavus* by dietary means, since cotton itself is not a food product for human consumption. There is minimal dietary exposure to *Aspergillus flavus* from cottonseed. There is no mechanism for *Aspergillus flavus* to be transferred from the seed to animal products and there is no evidence that the fungus readily contaminates meat or milk. Seed is typically extracted for oil with hexane and that process kills the fungus. Furthermore, applications of *Aspergillus flavus* AF36 do not increase the indigenous populations of *Aspergillus flavus* associated with the harvested crop. The applications merely alter the composition of the fungal community associated with the mature crop so that aflatoxin producing strains are far less frequent. The result is a much lower incidence of aflatoxins in the crop and in the environment associated with the developing and mature crop.

ii. *Drinking water. Aspergillus flavus* AF36 is a naturally occurring organism that is already widespread in the environment and is not considered to be a risk to drinking water. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure of *Aspergillus flavus* through the drinking

water. Applications of *Aspergillus flavus* AF36 do not increase the long-term populations of *Aspergillus flavus* in the environment, and thus are not expected to influence the relationship of *Aspergillus flavus* to water sources. Applications merely change the composition of the *Aspergillus flavus* community so that aflatoxin producing strains are less common in the environment.

2. *Non-dietary exposure.*The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant and is not expected to present any risk of adverse health effects.

E. Cumulative Exposure

There are no other registered products containing *Aspergillus flavus* AF36 or any other isolates (strains) of the microbial active ingredient. Data submitted show that the fungal metabolite of concern, which is aflatoxin, is not produced by *Aspergillus flavus* AF36 in the crop or in artificial media in the lab. When applied prior to flowering, *Aspergillus flavus* AF36 has been shown to exclude aflatoxin producing fungi competitively from the developing crop and to reduce aflatoxin contamination of cottonseed. Data show that the proposed use will not result in appreciable increases in the long-term population of *Aspergillus flavus* on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

F. Safety Determination

1. *U.S. population. Aspergillus flavus* AF36 is a naturally occurring organism. This isolate has low toxicity as demonstrated by the acute oral toxicity study in rats. *Aspergillus flavus* is ubiquitous throughout the hot desert valleys in Arizona. Studies have shown that treatment of cotton fields just prior to flowering with sterile wheat seed colonized by *Aspergillus flavus* AF36 at 10 lb per acre does not increase the long-term populations of *Aspergillus flavus* either on the crop at maturity or in the soil 1 year after application. Based on this information, Interregional Research Project Number–4 is of the opinion that the aggregate exposure to *Aspergillus flavus* over a lifetime should not change with application of *Aspergillus flavus* AF36, and exposure to both aflatoxin producing *Aspergillus flavus* strains and aflatoxin should decrease. This should be beneficial to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to *Aspergillus flavus* AF36.

2. *Infants and children.* Based on the lack of toxicity and natural occurrence, there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to *Aspergillus flavus* AF36. Exempting *Aspergillus flavus* AF36 from the requirement of a tolerance should pose no significant risk to humans or the environment.

G. Effects on the Immune and Endocrine Systems

Aspergillus flavus AF36 is a naturally occurring organism, which does not produce aflatoxin, and is thus safer than the *Aspergillus flavus* isolates that produce aflatoxin. To date there is no evidence to suggest that *Aspergillus flavus* AF36 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Efficacy

Existence of aflatoxins in the environment is a public health hazard. Data were submitted to demonstrate that proper use of *Aspergillus flavus* AF36 results in reductions in the average aflatoxin producing potential of fungi resident in treated areas and in reductions in the quantity of aflatoxins in crops. In field tests prior to 1996, the aflatoxin content of cottonseed was shown to be inversely related to the proportion of the *Aspergillus flavus* community on the crop composed of *Aspergillus flavus* AF36. Detailed analyses of the aflatoxin content of commercial fields from 1996 through 1998 confirmed that reduced aflatoxin levels were associated with displacement of aflatoxin producers by *Aspergillus flavus* AF36 from treated crops and that treatments were associated with up to 90% reductions in crop aflatoxin content.

Efficacy of applications of *Aspergillus flavus* AF36 in displacing aflatoxin producers was demonstrated for fungal communities both on cottonseed from treated crops at harvest and in soils of treated fields 1 year after treatment. This included cotton crops treated in 1996 (112 acres treated), 1997 (463 acres treated), 1998 (499 acres), 1999 (10,488 acres), 2000 (16,725 acres), and 2001 (19,975 acres treated). The proportion of *Aspergillus flavus* communities composed of *Aspergillus flavus* AF36 indicates the extent to which aflatoxin producers were displaced. In 1996 average incidence of AF36 on treated crops was 88.5% and in the soil, 1 year after treatment, incidence of AF36 was 85.2%. Incidences of AF36 on treated crops were 78% and 67% in 1997 and 1998, respectively, and in soil 1 year after treatment, AF36 incidences were 72% and 77%, respectively. Successful displacement was also observed as the acreage treated rapidly expanded from 1999 to 2001 with average incidences of AF36 on treated crops ranging from 57% in 1999 to 66% in 2001.

Aflatoxin-producing S strain isolates of *Aspergillus flavus* are prominent in soils of cotton producing areas of Arizona and south Texas. They produce more aflatoxins than other *Aspergillus flavus* isolates such as the non-aflatoxin-producing L strain *Aspergillus flavus* AF36. Applications of AF36 during the experimental program were effective at displacing the high aflatoxin producing S strain of *Aspergillus flavus*. During the course of the experimental use program, *Aspergillus flavus* AF36 also caused long-term reductions in the aflatoxin producing potential of fungal communities in agricultural fields. *Aspergillus flavus* AF36 retained atoxigenicity (failure to produce aflatoxins) upon repeated reisolation from treated fields 1, 2, or 3 years after treatment. Thus, there was a long-term reduction in the potential of fungal communities to produce aflatoxins in treated areas. The average aflatoxin producing potential of *Aspergillus flavus* communities resident in soils of treated fields was reduced on average 73% 1 year after treatment over the 3 year period (1996 to 1999). S strain isolates, which produced very high levels of aflatoxins, with field averages ranging from 7,100 ppb, aflatoxin to 22,700 ppb, aflatoxin, were effectively displaced. Their incidence was reduced from initially composing 46% of *Aspergillus flavus* soil communities to composing on average of 11%.

I. Existing Tolerances

The registrant is not aware of any existing tolerances or tolerance exemptions for *Aspergillus flavus* AF36, other than the temporary tolerance exemption on cotton (40 CFR 180.1206) in conjunction with an EUP, which expires on December 30, 2004.

J. International Tolerances

There are no Codex maximum residue levels established for residues of *Aspergillus flavus* AF36. *Aspergillus flavus* AF36 containing products are presently not registered for pest control outside of the United States.

[FR Doc. 03–3696 Filed 2–13–03; 8:45 am]

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